EDITORIAL

Informed Consent for Surgical Research

As in clinical practice, the proper implementation of informed consent in research is critical and regulated by local laws and international treaties. In addition, research protocols must be evaluated by an independent ethics committee, which also evaluates the informed consent form (ICF) and its implementation.

ICF Features in Research

The ICF must be designed specifically for the research being conducted. It is completely independent of the consent given in clinical practice, and should not be replaced by the forms that patients fill out when registering at many institutions, which indicate that their data may be used for research.

It is essential to understand the nature of the research to be undertaken and to assess the research procedures and their potential risks. The following questions can be asked: Is the study changing current practice and will there be a specific intervention? Will a standard treatment be used and is the study just about collecting data?

To illustrate this point, two entirely different scenarios could be proposed for the research on surgical outcomes in patients with diverticular disease and colovesical fistula treated laparoscopically:

- In the event of investigating the results of a newly developed variant (e.g. a modification in the manner of performing the anastomosis, a change in the analgesic modality, technical or perioperative management), an interventional clinical study is being considered. In such a scenario, the risk is increased, and the differences with the standard treatment, the medical necessity of the investigation, the nature of the intervention, and the risks involved must be explained in detail in the ICF. Furthermore, the undertaking of such an interventional clinical study may necessitate the procurement of insurance coverage.
- In contrast, if the surgical outcome of the standard treatment is to be evaluated, without any intervention in the study, the research involves risks only due to the data handling. In this scenario, the risk is lower, and the ICF must specify that the patient will receive the standard treatment and that the research consists of obtaining and analyzing data. In the context of observational studies, it is not necessary to explicitly delineate in the ICF the surgical intervention to be undertaken and the risks associated with the procedure, as these considerations are typically addressed in the informed consent document generally obtained for surgical intervention.

When is an ICF required for clinical research?

The necessity of obtaining an ICF is determined by the inherent risk level of the research, as stipulated by the Human Health Research Law (Law 3301/09 of the Ciudad Autónoma de Buenos Aires) and the Resolution 1480/2011 of the National Ministry of Health. The classification of risk categories is as follows:

1-Risk-free research: This type of research includes observational studies with public domain databases that are completely anonymized, making it impossible to establish the identity of individuals. For example, an epidemiological study on the prevalence of colorectal cancer in Argentina that was conducted using anonymous data provided by the Ministry of Health. Research of this nature does not require the use of an ICF.

2-Minimal risk research: It includes studies in which the probability of harm is analogous to that of daily life. The majority of observational studies conducted in the field of surgery fall under this category. A retrospective cohort study on the oncologic outcomes of patients undergoing surgery for rectal cancer serves as an example. In such instances, the risk is determined by data management. This type of study necessitates the acquisition of an ICF. However, the Ethics Committee may grant an exception to the requirement of obtaining consent, provided that the following three criteria are met:

- The research is impracticable without the ICF exception.
- The research involves minimal risk.
- Research is of significant value to society.

The points must be duly justified in the research protocol, typically in the ethical considerations section. Ultimately, the decision to apply the exception is determined by the local Ethics Committee.

3-Major risk research: It usually involves interventional studies and always requires the ICF.

Minimum ICF Elements

These are some basic elements that should be expanded according to each particular investigation.

- Start by inviting participation: ¨*because you have/have been diagnosed with...*¨
- The objectives of the study must be explained.
- The study should be described in a simple and concise manner.
- Explain what the subject's participation in the study entails and the subject's responsibilities.
- Explain that participation is completely voluntary. If the patient does not wish to participate, his or her physician will continue with the usual care and the refusal will not cause inconvenience.
- Mention the existence of other therapeutic options in case the patient decides not to participate in the study.
- Describe in simple terms the risks associated with the different study procedures.
- Specify that there will be no cost to the patient.
- Confidentiality. Mention Law 25 326 and list its scope.
- Provide the participant with information about the National Directorate of Personal Data.
- Who will have access to the data?
- Premature end of the study. Reasons that could cause the research or the participant's involvement may be brought to a

premature end must be specified. In the event of interruption for non-medical reasons, the reasons will be explained and all precautions will be taken to ensure that the participant's health is not adversely affected.

- Provide information on the principal investigator and the Ethics Committee.
- Signature page with date and time.

The subject is vast and many aspects remain unaddressed, so the reader can consult international treaties such as the *International Ethical Guidelines for Health-Related Research Involving Human Subjects*, a committee developed by CIOMS in 2016. You can also contact the research department of your center.

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